CLAIMS

1. A device for performing diagnostic assays of biological fluids for molecules contained therein comprising a container dividable into at least two chambers,

a first chamber comprising a means for absorbing fluid in communication with antibody or antigen impregnated matrix material, said impregnated matrix material being accessible to the exterior of said first chamber through an aperture in the roof of said first chamber;

a second chamber communicating with said first chamber and comprising a chemical means for absorbing moisture from said first chamber;

a means for pressure equilibration of said first and second chambers;

a filter support means situated above said antibody or antigen impregnated matrix material and in communication with said impregnated matrix material through said aperture in said roof of said first chamber, comprising filter material affixed to said support means for removing interfering substances present in said biological fluids and providing chemicals to said impregnated matrix material for coaction therewith to effect the detection of said molecules.

2. A device as described in Claim 1 wherein said means for absorbing fluid comprises a layer of porous material, and a mid-layer of material, said mid-layer material being situated between said antibody or antigen impregnated matrix material and said porous material.

3. A device as described in Claim 2 wherein said impregnated matrix material further comprises reagents selected from the group consisting of hormones, hormone receptors, enzymes, and derivatives or combinations thereof.

4. A device as described in Claim 3 wherein said impregnated matrix material comprises antibody or antigen absorbed onto said material comprising charging a solution containing said antibody or antigen, and deflecting said charged solution in a defined pattern onto said material.

5. A device as described in Claim 3 wherein said aperture in said roof of said first chamber is funnel shaped.

6. A device as described in Claim 5 wherein said filter support means is funnel shaped.

7. A device as described in Claim 6 wherein said chemicals provided by said filter material are proteinacious materials.

8. A device as described in Claim 7 wherein said chemicals provided by said filter material are proteinacious materials selected from the group consisting of antibody, antibody-enzyme conjugates, and enzyme substrates.

9. A device as described in Claim 8 wherein said chemicals provided by said filter material for coaction for said impregnated matrix material comprises associating said chemicals with said filter material by contacting said filter material with said chemicals wherein said chemicals are in powder form.

10. A method for impregnating immunochemicals onto matrix material useful in immunodiagnostic assays comprising dissolving said immunochemicals in solution, forming a thin stream of said solution, fragmenting said thin stream into droplets, applying a charge to said droplets, passing said charged droplets through an electric field thereby deflexing said droplets in a predetermined pattern onto said matrix material.

11. A method as defined in Claim 10 wherein said immunochemical reagents in said solution are selected from the group consisting of antibody, antigen, and combinations or derivatives of these molecules.

12. A method of assaying fluid for one or more molecules contained therein comprising:

one or more antibody molecules correspondingly reactive with said one or more molecules in said fluid;

one or more traceable second antibody molecules also correspondingly reactive with said one or more molecules in said fluid;

one or more third antibody molecules correspondingly reactive with said one or more traceable second antibodies;

wherein said one or more first antibody molecules and said one or more third antibody molecules are impregnated onto a porous matrix material in a defined orientation; and

forming a filtrate of said fluids by applying said fluids to a filtering means for removing interfering substances from said fluids and providing blocking agents to said filtrate;

coating said matrix material with said blocking agents and forming one or more complexes comprising said one or more first antibody molecules and said one or more corresponding molecules in said fluid comprising contacting said filtrate with said matrix material whereupon said one or more molecules in said fluid bind to said one or more first antibodies, and said blocking agent binds to said matrix material;

removing excess filtrate from said matrix material by contacting and retaining said excess filtrate with absorbent material;

determining the presence and/or amount of said one or more complexes comprising contacting said matrix material with one or more traceable second antibodies having binding specificities for said corresponding one or more molecules bound to said one or more first antibodies;

removing excess traceable second antibody;

adding a solution to said matrix material containing enzyme substrate for binding to said traceable second antibodies and revealing said complexes and removing excess substrate solution.

13. A method as described in Claim 12 wherein said one or more first antibody molecules correspondingly binds one or more hormone antigens.

14. A method as described in Claim 13 wherein said one or more traceable second antibody molecules bind to epitopes on said hormone antigens different from epitopes that said first antibodies are bound to.

15. A method as described in Claim 14 wherein said first and third antibodies are of the same immunoglobulin class.

16. A method as described in Claim 15 wherein said blocking agents are proteins.

17. A method as described in Claim 16 wherein said absorbent material comprises a layer of porous material, and a mid-layer of material, said mid-layer material being situated between said matrix material and said porous material.

18. A method as described in Claim 17 wherein said one or more traceable second antibody molecules comprise one or more second antibodies bound to enzyme.

19. A method as described in Claim 18 wherein said enzyme bound to said one or more traceable second antibody molecules hydrolyzes a substrate producing a color indicative of the presence of said complex.

20. A method as described in Claim 17 wherein said one or more traceable second antibodies is bound to a different enzyme.

21. A method as described in Claim 19 wherein one or more enzymes hydrolyze different substrates producing different colors indicative of the presence of different hormone complexes formed on said matrix material.

22. A device for performing diagnostic assays of biological fluids from molecules contained therein comprising a container,

a means for absorbing fluid situated in said container and in communication with antibody or antigen impregnated matrix material, said impregnated matrix material being accessible to the exterior of said container through a funnel shaped aperture in the roof of said container;

a chemical means associated with said container for absorbing moisture;

a funnel shaped filter support means situated above said antibody or antigen impregnated matrix material, and in communication with said matrix material through said aperture and said roof of said container, comprising filter material affixed to said support means for removing interfering substances present in said biological fluids and providing protein to said impregnated matrix material for coaction therewith to effect the detection of said molecules.

23. A device as described in Claim 22 wherein said means for absorbing fluid comprises a layer of porous material, and a mid-layer of material, said mid-layer being situated between said antibody or antigen impregnated matrix material and said porous material.

24. A device as described in Claim 23 wherein said impregnated matrix material further comprises reagents selected from the group consisting of hormones, hormone receptors, enzymes, and derivatives or combinations thereof.

25. A device as described in Claim 24 wherein said impregnated matrix material comprises antibody or antigen absorbed onto said material comprising a solution containing said antibody or antigen, and deflecting said charged solution in a defined pattern onto said material.

TABLE 1

ICON (Hybritech, Inc.), hCG	Kit requires storage at 2-8 C Antibody Enzyme Conjugate should be stored at 2-8 C
RAMP (Monoclonal Antibodes, Inc.), hCG	Kit should be kept at 2-8 C
TEST PACK (Abbott Labs, Inc.), hCG	

TABLE 2

DIAGNOSTIC DEVICES	METHOD	SOURCE OF ANTIBODY	REACTION TIME	SENSITIVITY
Present Device	EIA, Coated Membrane	Mouse Monoclone	2 Min.	20 mIU/ml (1st IRP)
TEST PACK hCG-URINE Abbott Laboratories	EIA, Coated Filter	Mouse Monoclone	3 Min.	50 mIU/ml (1st IRP)
ICON® HCG-Urine Hybritech	EIA, Coated Membrane	Mouse Monoclone	3 Min.	50 mIU/ml (1st IRP)
TANDEM Visual HCG (Urine) Hybritech	EIA, Coated Bead	Mouse Monoclone	45 Min.	50 mIU/ml (1st IRP)
RAMP™ Urine hCG Assay Monoclonal Antibodies, Inc.	EIA, Coated Membrane	Mouse Monoclone	3 Min.	50 mIU/ml (1st IRP)
DUOCLONE™ Slide Organon	Latex Agglutination	Mouse Monoclone	3 Min.	500 mIU/ml (2nd I.S.)
BETA Quik Stat Pacific Biotech, Inc.	EIA, Coated Tube	Mouse Monoclone	5 Min.	25 mIU/ml (2nd I.S.)